Saving Genus Claims for Antibody Patents: What We Can Learn From the Foreign Jurisdictions

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ABSTRACT

In the United States, therapeutic antibodies play a key role in the innovations for life-saving therapies. Genus claims—broad claims that cover a group of related species – are widely used in antibody patents, allowing the patentee to obtain broad protection of their inventions. However, a recent line of Federal Circuit decisions has created a higher bar to obtaining patent protection for antibodies. Specifically, it is now nearly impossible to maintain an antibody genus claim. Noteworthy, the United States' treatment for antibody claims is diverging from other major jurisdictions in the world.

This Article argues the Supreme Court and Congress should reverse the trend of the over-restrictive disclosure requirement for antibody patents. This Article further discusses why the more restrictive test is harmful, what we can learn from foreign antibody protection, and provides proposed solutions to encourage development of innovative therapeutic antibodies.

I. INTRODUCTION

In 1986, the United States Food and Drug Administration (US FDA) approved the first monoclonal antibody, a man-made protein that acts like an antibody when injected into human bodies.[1] Since then, therapeutic antibodies have experienced explosive growth.[2] Antibodies have recently dominated the global pharmaceutical market and have become best-selling drugs,[3] such as Adalimumab (Humira), Nivolumab (Opdivo), Pembrolizumab (Keytruda), Trastuzumab (Herceptin).[4] As the best-selling drug of 2020, Humira is predicted to maintain this dominance

1. *See* Ruei-Min Lu et al., *Development of therapeutic antibodies for the treatment of diseases*, 27 J. BIOMEDICAL SCI. 1, 1 (2020), https://doi.org/10.1186/s12929-019-0592-z [https://perma.cc/FZ4E-439U].
2. *Id.*
3. *Id.*
4. *See id.* at 9.

through 2024.[5] Among the top 50 drugs expected to be the top-sellers by 2024, 21 are fully human monoclonal antibodies.[6] The global therapeutic monoclonal antibody market was valued at more than $117 billion in 2021 and is expected to surpass $524 billion by 2030.[7]

Patent protection for antibody inventions is important to biopharmaceutical companies as each patent family covering antibody-based drugs can be worth billions of dollars.[8] Securing patent protection can motivate companies to devote more time and money to boost the research and development of therapeutic antibodies. Because the antibody technology and antibody market are growing rapidly, it is crucial for biopharmaceutical companies to patent their newly developed therapeutic antibodies as early as possible to protect the underlying invention.[9]

To obtain a valid patent in the area of antibodies, the application must meet stringent disclosure requirements.[10] Indeed, recent judicial decisions adopt a much stricter standard for disclosure than other types of inventions.[11] Thus, biopharmaceutical companies have to wait longer to file patent applications—specifically, until sufficient data is obtained through the research and tests on representative numbers of antibodies.[12] The drug industry also faces challenges when large numbers of issued antibody patents may be

5. Stephanie Prezioso, *The Top 7 Monoclonal Antibody Drugs in 2024 will Target Inflammation and Cancer*, BENCHSCI, https://blog.benchsci.com/the-top-7-monoclonal-antibody-drugs-in-2024-will-target-inflammation-and-cancer [https://perma.cc/GNR8-8PD6] (last updated Aug. 11, 2021).

6. *Id.*

7. Precedence Research, *Monoclonal Antibodies Market Size to Hit US$ 524.68 Bn By 2030*, GLOBENEWSWIRE (May 23, 2022, 10:30 AM), https://www.globenewswire.com/en/news-release/2022/05/23/2448585/0/en/Monoclonal-Antibodies-Market-Size-to-Hit-US-524-68-Bn-By-2030.html [https://perma.cc/9U4X-6V9T].

8. Karen Carroll & Sharad Bijanki, *The Evolution of Antibody Patents* IPWATCHDOG (Oct. 8, 2018, 07:30 AM), https://www.ipwatchdog.com/2018/10/08/evolution-antibody-patents/id=101971/ [https://perma.cc/6Q9M-VZLP].

9. *See id.*

10. U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (§ 608, 9th ed. 2023).

11. *See* Barbara Rigby, *United States: Stricter Patent Requirements In The US For Antibodies And Beyond* (May 30, 2018), https://www.mondaq.com/unitedstates/patent/705730/stricter-patent-requirements-in-the-us-for-antibodies-and-beyond [https://perma.cc/D3JC-W5BY].

12. *See* Carroll & Bijanki, *supra* note 8.

declared invalid, making obtaining and enforcing antibody patents increasingly difficult.[13]

Scholars and other commentators have discussed the evolvements of antibody case law regarding disclosure requirements.[14] A few scholars criticized the over-restrictive disclosure requirement in view of recent judicial decisions.[15] However, of all the articles, very few discuss the treatment of antibody claims in foreign countries in sufficient detail. This Article will provide an in-depth analysis of the statutes and case law in foreign countries. It contends the U.S. should adopt a more lenient standard for disclosure requirements in order to promote continued innovation in the field of antibody drugs. This Article compares the treatment for antibody patents in the U.S. and foreign countries, discusses why the other legal systems may treat the disclosure requirement for antibody patents more effectively, and how we should change current U.S. law to solve the issue.

This Article covers the following topics relating to antibody patents: the development of therapeutic antibodies and the use of genus claims in antibody patents, current laws regarding disclosure requirements for genus claims in the U.S. and foreign jurisdictions, how U.S. and foreign jurisdictions deal with the disclosure requirements for antibody patents, the heightened standard for genus claims which poses a challenge to

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13. *Is There Any Hope For Antibody Patents in the United States?*, OBLON (Jan. 25, 2022), https://www.oblon.com/is-there-any-hope-for-antibody-patents-in-the-united-states [https://perma.cc/MB67-HBH7].

14. *See e.g.*, Dmitry Karshtedt et al., *Article: The Death of the Genus Claim*, 35 HARV. J. LAW & TEC., 1 (2021); Sean Tu & Christopher M. Holman, *Antibody Claims and the Evolution of the Written Description / Enablement Requirement*, 63 IDEA 84, 85 (Apr. 20, 2022), https://ssrn.com/abstract=4088589; Theodore Teng et al., *Antibody Patent Evolution*, 13 IEE PULSE 37 (Oct. 27, 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4264899; Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L. J. 994, 1046–47 (2023); Anna N. Lukacher, *The Future of Patenting Antibodies After Amgen v. Sanofi*, 58 IDEA: J. FRANKLIN PIERCE FOR INTELL. PROP 95, 109 (2017); Shahrokh Falati, *Eviscerating Patent Scope*, 21 UIC REV. INTELL. PROP. L. 121, 137 (2022); Hayley LeBlanc, *Putting the CAR-T Before the Horse: How Much Disclosure is Required Under Section 112(a) for Biotechnological Inventions?*, 24 TUL. J. TECH & INTELL. PROP. 251, 258–59 (2022); Jeffie A. Kopczynski, *A New Era for § 112? Exploring Recent Developments in the Written Description Requirement as Applied to Biotechnology Inventions*, 16 HARV. J. LAW & TEC. 229, 239 (2002); Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1247 (2000).

15. *See e.g.*, Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J. LAW & TEC., 1, 17–18 (2021) (arguing that the heightened disclosure requirements should be rejected because of lack of statutory basis and conflicts with Supreme Court Jurisprudence); Shahrokh Falati, *Eviscerating Patent Scope*, 21 UIC REV. INTELL. PROP. L. 121, 147-148 (2022); Sam Habein, *The United States Stands Alone: A Divergence in the Treatment of Genus Claims in Pharmaceutical Patents*, 22 UIC REV. INTELL. PROP. L. 97, 101 (2022); Katie Albanese, *When is Enough? What Constitutes Adequate Written Description of a Genus*, 29 FED. CIR. B.J. 343, 347–51 (2020).

biopharmaceutical companies, and potential solutions based on policy suggestions and modeling other countries.

Further, this Article contends that the Supreme Court should review and reverse the U.S. Court of Appeals for the Federal Circuit (the court with exclusive jurisdiction over patent appeals)'s recent ruling in *Amgen Inc. v. Sanofi*,[16] because the court created a new, heightened enablement test that thwarts the aims of patent law. Based on an in-depth analysis of the treatment of antibody patents in the European Union, Japan, and Canada, it is clear that the current approach in the U.S. not only diverges from those countries but does not sensibly promote innovation in the field of antibodies. The Article concludes by assessing potential solutions for U.S. law to encourage the continued invention and commercialization of antibodies.

Part I begins by providing necessary background information on what antibody drugs are, how they work, recent development for antibody drugs, and the use of genus claims in antibody patents. Part II explains statutes and current law regarding patent disclosure requirements in the U.S., Japan, European Union, and Canada. Part III discusses the challenges for antibody patent protection. It explores the Federal Circuit's recent ruling on antibody patents and its impact on pharmaceutical companies, antibody innovations, and the patent system. Part IV looks at the case law regarding antibody genus claims in Japan, the European Union, and Canada and their treatment that the U.S. can learn from. In Part V, potential solutions will be provided for consideration. Finally, Part VI concludes with a discussion of policy considerations regarding the restrictive disclosure standard for antibody patents.

A. Background of Therapeutic Antibodies

Antibodies are components of our immune system that can target, bind, and destroy specific antigens.[17] Therapeutic monoclonal antibodies are man-made proteins that act like antibodies when injected into our bodies.[18] Therapeutic monoclonal antibodies are able to target specific antigens and

16. Amgen Inc. v. Sanofi, 987 F.3d 1080 (Fed. Cir. 2021).
17. *Monoclonal Antibodies*, CLEVELAND CLINIC (Nov. 16, 2021), https://my.clevelandclinic.org/health/treatments/22246-monoclonal-antibodies [https://perma.cc/942U-AKZD].
18. *Id.*

are widely used to treat cancer and other deadly diseases.[19] Adalimumab (Humira), an anti-tumor necrosis factor α human antibody, is the first fully human therapeutic antibody.[20] Adalimumab is a biological disease modifier that binds explicitly to TNFα receptors—an inflammation-causing protein, and inhibits its reaction with other cells.[21] As AbbVie's immunology superstar and the first fully human monoclonal antibody approved by the US FDA,[22] Humira was the highest selling drug of 2020, generating a massive $19.8 billion in sales.[23] Adalimumab successfully reduces the symptoms of rheumatoid arthritis in adults, in addition to treating other diseases like psoriatic arthritis, ankylosing spondylitis, and Crohn's disease.[24] With the advance of antibody technology, current antibody drugs have fewer side effects due to their higher specificity.[25] Therapeutic antibodies are now the predominant class of newly discovered medications.[26]

Developing therapeutic antibodies is a complex process. Two of the key steps are: (1) identifying the target antigen that causes the disease, and (2) selecting the antibodies capable of specific binding with the target antigen.[27] Capable antibodies are selected from "antibody libraries"— a pool which contains an extensive amount of existing antibodies.[28] In order to find the most highly specific antibodies, repeated rounds of selection are needed.[29] An example of this is the development of treatments for the Middle East respiratory syndrome coronavirus (MERS-CoV).[30] To successfully identify the specific antibodies to treat MERS-CoV, the research group selected from an antibody library containing 10^9 antibodies.[31] This process of discovering, developing, and testing antibody drugs can take

19. *Therapeutic Antibody Overview*, CREATIVE BIOLABS, https://www.creativebiolabs.net/therapeutic-antibody-overview.html [https://perma.cc/7YE4-PYR5].
20. Lu et al., *supra* note 1, at 7.
21. *What Is HUMIRA® (adalimumab): Crohn's Biologic Treatment*, HUMIRA ADALIMUMAB, https://www.humira.com/crohns/about-humira/what-is-humira [https://perma.cc/3H22-FQUM].
22. Lu et al., *supra* note 1, at 7.
23. Skylar Kenney, *Pharmacy Fact: What is the Best-Selling Prescription Drug?*, PHARMACY TIMES (Aug. 20, 2021), https://www.pharmacytimes.com/view/pharmacy-fact-what-is-the-best-selling-prescription-drug [https://perma.cc/KGU5-DE6L].
24. Lu et al., *supra* note 1, at 8.
25. *See id*. at 1.
26. *See id*.
27. *See Monoclonal Antibodies and Their Side Effects*, AM. CANCER SOC'Y, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/monoclonal-antibodies.html [https://perma.cc/6ULE-YSNG].
28. *See* Lu et al., *supra* note 1, at 14.
29. *Id.*
30. *Id.* at 15
31. *Id.*

up to 20 years,[32] and the cost of bringing a new drug to market is between $2 and $3 billion.[33] Therefore, biopharmaceutical companies seek to obtain the broadest scope of patent protection after undergoing the long and costly development of novel therapeutic antibodies.

B. Overview of Genus Claims in Antibody Patents

A patent claim is the legal definition of the invention drafted by the patent practitioner.[34] A patent claim defines the boundaries of an invention and the subjective matter that is sought to be protected.[35] In order to get the broadest protection, patent practitioners generally "draft those claims as broadly as the [patent] law . . . allows."[36] One of the strategies is the use of a "genus claim"—"a broad claim that covers" not just one species but a group of related species.[37] Genus claims are widely used in the biopharmaceutical industry, especially in antibody patents, allowing the patentee to obtain broad protection for derivate species.[38]

Genus claims may be function or target-defined claims (e.g., "an antibody capable of binding to antigen X" or "an antibody that can achieve Y function").[39] However, as the case law has evolved, courts have almost invariably rejected genus claims in antibody patents under 35 U.S.C. § 112(a) for failure to meet the disclosure requirement.[40]

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32. *Antibodies at work*, REGENERON, https://www.regeneron.com/science/antibodies [https://perma.cc/6SBW-P8FK].

33. Thomas Sullivan, *A Tough Road: Cost To Develop One New Drug Is $ 2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%,* POLICY & MED. (Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html [https://perma.cc/UMZ9-BEAB].

34. Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J. LAW & TECH., 1, 3 (2021).

35. *See* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 639 (5th ed. 2019).

36. *See* Karshtedt et al., *supra* note 34, at 3.

37. *Id.*

38. *See id.*

39. *See* Christopher E. Loh, *Antibody Claims: Patent Eligibility and Written Description Issues*, LEXISNEXIS (Mar. 10, 2020), https://www.lexisnexis.com/community/insights/legal/practical-guidance-journal/b/pa/posts/antibody-claims-patent-eligibility-and-written-description-issues [https://perma.cc/S2ZT-R2FU].

40. Karshtedt et al., *supra* note 34, at 4.

II. DISCLOSURE REQUIREMENT FOR ANTIBODY PATENTS

A. U.S. Law

35 U.S.C. § 112 sets forth the "enablement requirement" and "written description requirement" for patent specifications.[41]

1. Enablement Requirement

To obtain a patent, an applicant must disclose to the public how to make and use the claimed invention in exchange for a 20-year monopoly.[42] In exchange, "[the public] gets two things: (1) use of the invention once the patent term expires, and (2) . . . disclosure . . . about . . . how to make and use [the invention once] the patent document publishes."[43] 35 U.S.C. § 112(a) states a patent specification (the descriptive part of the patent application) shall describe "the manner and process of making . . . [the invention], in such full, clear, concise terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]."[44] The enablement requirement aims to "ensure that the invention is communicated to the interested public in a meaningful way."[45] As interpreted by the courts, the enablement requirement demands that a patent specification provide sufficient disclosure to allow a person with ordinary skills in the art "to make and use [the] invention . . . without undue experimentation."[46] Enablement is not precluded even though some experimentation is required to make the invention, as long as it is not "unduly extensive."[47]

In *In re Wands*, the Federal Circuit set forth eight factors to determine whether a patent specification met the enablement requirement, which is regularly applied in the field of biotechnology and pharmaceuticals.[48] As stated by the court, these factors are as follows:

> (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the

41. Loh, *supra* note 39.

42. Shannon M. Patrick & Stacy Lewis, *The CCPA's Lasting Impact on U.S. Patent Law – An Examination of CCPA Enablement Decisions*, FINNEGAN (Nov. 4, 2022), https://www.finnegan.com/en/insights/blogs/prosecution-first/the-ccpas-lasting-impact-on-us-patent-law-an-examination-of-ccpa-enablement-decisions.html [https://perma.cc/MY8Q-5C9K].

43. Karshtedt et al., *supra* note 34, at 5 (citation omitted).

44. 35 U.S.C. § 112(a).

45. MPEP (9th ed. Rev. 07.2022, Feb. 2023), § 2164.

46. *See In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

47. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984).

48. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

> nature of the invention; (5) the state of the prior art (preexisting knowledge and technology already available to the public); (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.[49]

In the "unpredictable arts," such as biopharmaceuticals, the patent specification is required to provide a more detailed disclosure because a person with ordinary skills in the art cannot anticipate whether a process "that works for one . . . species of [the genus] will work for others."[50] *In re Wands* further held that because the nature of monoclonal antibody technology involved screening, the antibody screening process was routine and was unlikely to be considered undue experimentation.[51]

2. Written Description Requirement

Another requirement under the Patent Act is the written description requirement. 35 U.S.C. § 112(a) states a patent specification "shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]."[52] Because the enablement and written description requirements come from the same paragraph of the Patent Act, there has been a long-standing debate about whether enablement and written description are two separate requirements. In the seminal case *Ariad Pharm., Inc. v. Eli Lilly & Co*., the Federal Circuit held the written description requirement was separate and distinct from the enablement requirement.[53] The written description requirement demands that a patent specification provide sufficient information to convince a person of ordinary skill in the art that the inventors had "possession of the invention" at the time that the application was filed.[54]

Ariad set forth a test for the "possession" standard: "a representative number of species" or shared structure common to the claimed genus is required to show the possession of the genus.[55] In *Ariad*, the plaintiff identified a transcription factor called NF-êB, which can regulate gene

49. *Id.*
50. Karshtedt et al., *supra* note 34, at 9 (citation omitted).
51. *See Wands,* 858 F.2d at 740.
52. 35 U.S.C. § 112(a).
53. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010).
54. *See* ADELMAN ET AL., *supra* note 35, at 448.
55. *Ariad Pharm., Inc.*, 598 F.3d at 1350.

expression.[56] Ariad then filed a patent application describing several methods of reducing NF-êB activity that could alleviate "harmful symptoms of certain diseases."[57] The claims were genus claims that described the use of all substances to achieve the desired function.[58] The court noted that simply "claim[ing] a desired result . . . without describing [the] species that . . . achieve[d] the result" is not adequate.[59] An adequate description of a genus requires "the disclosure of a representative number of species falling within the scope of the genus or structural features common to the members of the genus," such that a person of ordinary skill in the art can "visualize or recognize" the genus members.[60] The court noted that sufficient description requires a precise description "to distinguish the genus from other materials," including "structure, formula, . . . physical properties, or other properties."[61] However, current law is unclear about how many or what types of species need to be disclosed to meet the written description requirement for claiming a genus.[62]

B. Japanese Law

In Japan, the Patent Act Article sets forth two requirements for sufficient disclosure: the enablement requirement and the support requirement.[63] Japan's enablement requirement is equivalent to the U.S. enablement requirement; the support requirement is equivalent to the U.S. written description requirement.

1. Enablement Requirement

Patent Act Article 36(4)(i) states that "the statement shall be clear and sufficient in such a manner as to enable any person ordinarily skilled in the art" to carry out the claimed invention.[64] If a person skilled in the art

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56. *Id.* at 1340.
57. *Id.*
58. *Id.* at 1341.
59. *Ariad Pharm., Inc.*, 598 F.3d at 1349.
60. *Id.* at 1350.
61. *Id.* (citation omitted).
62. Shahrokh Falati, *Eviscerating Patent Scope*, 21 UIC REV. INTELL. PROP. L. 121, 135 (2022), https://repository.law.uic.edu/cgi/viewcontent.cgi?article=1513&context=ripl [https://perma.cc/9TTS-MPG8].
63. *Antibody defined by its function is patentable?* NAGOYA INT'L IP FIRM (Aug. 31, 2022) [hereinafter Nagoya International], https://www.patent.gr.jp/english/news/shosai.html?id=1692465858612d92ca53fa2 [https://perma.cc/8EPL-WTPX].
64. *Examination Guidelines for Patent and Utility Model in Japan*, JAPAN PAT. OFF., pt. II, ch. 1, § 2-1, hereinafter Japan Patent Office], https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/document/index/all_e.pdf [https://perma.cc/ZY86-TZY3].

who intends to carry out the invention would have to "make trials and errors and/or complicated and sophisticated experimentation" beyond the reasonably expected extent, the specification fails to satisfy the enablement requirement.[65]

2. Support Requirement

Patent Act Article 36(6)(i) states that "a claimed invention shall be disclosed in the description."[66] In determining whether the patent description meets the support requirement, the examiner will look at whether the claimed invention exceeds "the extent of disclosure in the description to which a person skilled in the art would recognize that a problem to be solved by the invention would be actually solved."[67] If the claim and the specification does not substantially correspond with each other, the support requirement is not met.[68]

It is generally believed that the enablement and support requirements regarding pharmaceutical inventions under Japanese patent law are very strict.[69] The Japanese Patent Office (JPO) issued Examination Guidelines for Pharmaceutical Inventions in 2005, which addressed the enablement and support requirements.[70] Pharmaceutical inventions must disclose "pharmacological test data or the equivalent" in the specification to convey to a person skilled in the art that the inventors had possession of the invention.[71] Furthermore, the JPO doesn't accept post-filing data if the original specification fails to provide sufficient pharmacological data.[72]

In summary, the JPO has strict enablement and support requirements regarding patent disclosure, which are very similar to the disclosure requirements in the U.S. Patent Act. The JPO generally requires patent specifications to provide specific examples or convincing technical rationale

65. *Id.* pt. II, ch. 1, § 2-2.
66. *Id.* pt. II, ch. 1, § 1, 4.1.2.
67. *Id.* pt. II, ch. 2, § 2.1(3) (citation omitted).
68. *Id.* pt. II, ch. 2, § 2-2.
69. *Guidelines on Drafting Patent Application*, YANAGIDA & ASSOCIATES, http://www.yanagidapat.com/en/business/guidelines.html [https://perma.cc/SYM9-WRUN].
70. Kawaguti & Partners, *Examination Guidelines for Pat. Applications Relating to Pharm. Inventions in the Japan Pat. Off.*, https://www.kawaguti.gr.jp/aboutlaw/jp_practices/03_1.html [https://perma.cc/5TBT-JCHE].
71. *Id.*
72. *Id.*

to support the entire scope of claims.[73] Furthermore, specifications must disclose enough experimental data to prove the claimed inventions have actually been made.[74]

C. Law in the European Union

In Europe, applicants can file patent applications at a national level or at the European Patent Office (EPO).[75] The enactment of the European Patent Convention (EPC) provided the basis for patent law in Europe.[76]

The USPTO and the EPO have different standards for disclosure requirements for antibody patent applications.[77] EPC Article 83 defines the disclosure requirement: "[t]he European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art."[78] This requirement, called the "sufficiency requirement," is equivalent to the U.S. enablement requirement.[79] "The test [. . .] is whether it would be an 'undue burden' for a person skilled in the art to put the invention into effect."[80]

Guidelines for examination provided by the EPO state that "[a] detailed description of at least one way of carrying out the invention must be given."[81] The guidelines also state that one single example may suffice, but if the claims cover a broad field, the description must provide a number of examples or alternative embodiments.[82] The EPO does not require the patentee "to provide evidence that an antibody has actually been produced if the target is susceptible to routine methods of antibody production."[83]

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73. *See* YANAGIDA & ASSOCS., *supra* note 69.

74. *See id.*

75. Evelien Moorkens, et al., *An overview of pats. on therapeutic monoclonal antibodies in Eur.: are they a hurdle to biosimilar market entry?* (Apr. 19, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7188399/ [https://perma.cc/W8K7-UVLH].

76. *Id.*

77. Yifan Mao & Andrew Serafini, *Navigating Key Differences in Therapeutic Antibody Pat. Prot. Strategies Between the U.S. & Eur.*, JDSUPRA (Apr. 29, 2021), https://www.jdsupra.com/legalnews/navigating-keydifferences-in-8802999/ [https://perma.cc/7EKF-HLS6].

78. Convention on the Grant of Eur. Pats., art. 83, Oct. 5, 1973, 1065 U.N.T.S. 199, 279.

79. Louise Holliday, *Patenting antibodies in Eur.*, 1 MABS 386 (20 Let me know what you plan to do! 09), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726612/ [https://perma.cc/6VPD-9PWS].

80. *Id.*

81. *Guidelines for Examination: Part F, ch. III.1*, EUR. PAT. OFF., https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iii_1.htm [https://perma.cc/7TLS-UK8E].

82. *Id.*

83. Falati, *supra* note 62, at 137.

Furthermore, the EPO allows claims directed to the antibody only by describing its ability to bind a novel antigen without disclosing information for the antibody itself.[84] For example, the claims at issue in *Roche Diagnostics GmbH v. Medac Gesellschaft*, are functionally defined genus claims.[85] The claims recite "[a]n antibody which binds to the CD30 antigen and (a) releases sCD30 from Hodgkin's disease cells [. . . .]"[86] The patent only disclosed the preparation and analysis of one embodiment – Ki-4.[87] The EPO Boards of Appeal held the claims met the requirement of EPC Art. 83 without undue burden.[88] The court reasoned that a skilled person could have found the other antibodies having the same characteristics by carrying out the same laborious screening process as described in the patent.[89]

In summary, the EPO has a "sufficiency of disclosure" requirement equivalent to the U.S. "enablement" requirement.[90] However, the EPO does not have a written description requirement.[91] The EPO accepts functionally defined genus claims even though the patent only discloses the preparation and analysis of one example.[92] Overall, the EPO has a less restrictive disclosure requirement than the USPTO.

D. Canadian Law

In Canada, the disclosure requirement is covered in the Patent Act § 27(3)[93] and Patent Rules paragraph 60.[94] The Patent Act §27(3) demands a specification must:

84. Jonathan B. Fitzgerald et al., *Patenting Across Three Jurisdictions*, INTELL. PROP. MAG., Apr. 2020, 1, at 2, https://www.swlaw.com/assets/pdf/publications/2020/04/08/Patenting%20across%20three%20jurisdictionspdf.pdf [https://perma.cc/XVJ7-MPAW].

85. Roche Diagnostics GmbH v. Medac Gesellschaft für klinische Spezialpräparate mbH, Decision T 0877/03 - 3.3.4, Eur. Pat. Off. Boards of Appeal, 11 (Apr. 7, 2015) (Ger.) [hereinafter Roche Diagnostics Decision], https://www.epo.org/law-practice/case-law-appeals/pdf/t030877eu1.pdf [https://perma.cc/XMQ9-T63G].

86. *Id.* at 1.

87. *Id* at 15.

88. *Id* at 4.

89. *Id.* at 15.

90. Holliday, *supra* note 79.

91. Thomas J. Kowalski et al., *Dominating global intell. prop.: Overview of patentability in the USA, Eur. & Japan*, 9 J. COM. BIOTECHNOLOGY 305, 314 (2003).

92. *See* Roche Diagnostics Decision, *supra* note 85, at 15.

93. Patent Act, R.S.C. 1985, c. P-4, § 27(3) (Can.).

94. Patent Rules, SOR/96–423, ¶ 60 (Can.).

a. correctly and fully describe the invention and its operation or use as contemplated by the inventor; [and]
b. set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it [. . .][95]

As such, § 27(3)(a) is similar to the U.S. written description requirement, and § 27(3)(b) is similar to the U.S. enablement requirement.[96]

Patent Rules paragraph 60 demands that "claims must be clear and concise and must be fully supported by the description independently of any document referred to in the description."[97] Therefore, the scope of the claims must be supported by the specification.[98] Rejections typically arise when the scope of the claim is much broader than what is soundly predicted by the specification.[99]

Canada, like Europe, permits claiming an antibody specific for a novel antigen without disclosing a specific embodiment of such antibody if the antigen is sufficiently described.[100] To be novel, the antigen must not have been previously characterized.[101] This test is called the "newly characterized antigen" test in the U.S.[102] However, in 2017, the U.S. Federal Circuit rejected this test and held that an adequate written description must disclose enough information about the claimed antibody itself.[103]

Before 2009, Canada's disclosure requirement related to monoclonal antibodies generally required the specification to provide working examples describing the making of the claimed antibodies.[104] However, in 2009, the Canadian Intellectual Property Office (CIPO)'s Manual of Patent Office Practice was amended to change the standard of disclosure requirement.[105] If the general procedure for making a monoclonal antibody was known in

95. Patent Act, R.S.C. 1985, c P–4, § 27(3) (Can.).
96. Carmela De Luca & Anastassia Trifonova, *Pat. Disclosure Requirements for Therapeutic Antibody Pats.*, 27 EXP. OP. THERAPEUTIC PAT. 867, 868 (2017), http://dx.doi.org/10.1080/13543776.2017.1296950 [https://perma.cc/QL85-Q34U].
97. Patent Rules, SOR/96–423, ¶ 60 (Can.).
98. *See* Luca & Trifonova, *supra* note 96, at 868.
99. *Id*.
100. *Id*.
101. Fitzgerald et al., *supra* note 84, at 37.
102. *See* Amgen Inc. v. Sanofi, et al., 872 F.3d 1367, 1377 (Fed. Cir. 2017).
103. *Id.* at 1378.
104. Luca & Trifonova, *supra* note 96, at 868.
105. *Id*.

the art, detailed explanations for the procedures and working examples for the antibody were not strictly required to meet the disclosure requirement.[106] In a 2010 case, the Commissioner of Patents confirmed this standard by allowing claims directed to monoclonal antibodies without a working sample in the patent specification.[107]

In summary, Canada has a disclosure requirement regarding antibody patents similar to Europe and less restrictive than the United States.

III. CHALLENGES TO PROTECTING ANTIBODY PATENTS: GENUS CLAIMS FAIL IN COURT

Recent U.S. cases regarding antibody patents suggest an even more restrictive standard for written description and enablement requirements for genus claims.

A. Recent Cases: Rejecting Genus Claims on Written Description and Enablement Grounds

In *Amgen Inc. v. Sanofi* (2017), the Federal Circuit rejected the "newly characterized antigen" test, which had allowed claiming a genus of antibodies by disclosing a newly characterized antigen to which it binds.[108] The patents-in-suit were directed to antibodies used to reduce bad cholesterol in the bloodstream.[109] Since early 2005, Amgen began studying PCSK9, a naturally occurring protein that binds to bad cholesterol receptors (LDL receptors).[110] LDL receptors are responsible for removing bad cholesterol from the bloodstream.[111] The aim of the therapy is to reduce PCSK9 levels, thereby increasing the expression of LDL receptors and lowering the levels of bad cholesterol.[112]

Amgen developed an antibody drug that targeted and specifically bound to PCSK9.[113] The claims covered the whole genus of antibodies that bind

106. *Id*.
107. *See* Re Immunex Corp. Pat. App. No. 583,988, decision of the Comm'r of Pats., ¶ 31 (Can.), https://www.smartbiggar.ca/_Archives/files/Patent%20No.%20583,988.pdf [https://perma.cc/YTG9-LJBW].
108. *See Amgen Inc.*, 872 F.3d at 1376–78.
109. *Id.* at 1371.
110. *Id.*at 1371.
111. *Id.*
112. *Id.*
113. *Id.*

specific residues on PCSK9.[114] The specification disclosed the three-dimensional structure of two known antibodies that bind the residues on PCSK9.[115] Such disclosure would have been sufficient under the "newly characterized antigen" test, because the specification includes a description of the target protein PCSK9 and the part of PCSK9 the claimed antibodies bind to. However, the Federal Circuit rejected this test and held that an adequate written description must disclose enough information about the claimed antibody itself, such as by structure, formula, chemical name, physical or other properties.[116] In conclusion, the court reversed the established "newly characterized antigen" test for antibody patents and dramatically increased the criteria needed to meet the written description requirement.

In *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, the Federal Circuit raised doubts about the use of functional claimed language in genus claims.[117] Kite Pharma developed "a nucleic acid polymer encoding a chimeric T cell receptor" that can be used in therapeutics.[118] The chimeric T cell receptor contains a binding element—single-chain variable fragment (scFv).[119] scFv is a fusion protein capable of binding to selected therapeutic targets (i.e., CD19).[120] Therefore, the chimeric T cell receptor can carry out its therapeutic role due to the function of scFv. The scFv binding element was claimed according to its function as being capable of specifically binding to CD19.[121] However, the specification only disclosed two examples of scFv.[122] The court held the claims had insufficient written description for the full scope of the claimed genus.[123] The specification failed to provide a representative example of species or structural features common to the genus members to support the assertion that the inventors possessed the claimed invention.[124]

A second Federal Circuit decision in *Amgen Inc. v. Sanofi* created yet another hurdle with respect to the disclosure requirement. The claim at issue was a functionally defined genus claim: "an isolated monoclonal antibody" that binds to a particular region on a specific protein (i.e.,

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114. *Id.* at 1372.
115. *Id.*
116. *Amgen Inc*, 872 F.3d at 1378.
117. *See* Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1335–36 (Fed. Cir. 2021).
118. *Id* at 1333–34.
119. *Id.*
120. *Id.*
121. *See Juno Therapeutics*, 10 F.4th at 1340.
122. *Id.* at 1336.
123. *Id.* at 1340.
124. *Id.* at 1342.

PCSK9).[125] The court held the claim invalid.[126] However, the court's holding relied less on lack of written description, but more on lack of adequate enablement.[127] On remand from the first *Amgen v. Sanofi* Federal Circuit decision, the second jury found the defendant failed to prove the asserted claims were invalid for lack of disclosure.[128] The defendant moved for judgment as a matter of law ("JMOL") and the district court granted the motion.[129] Amgen then appealed to the Federal Circuit for the second time.[130]

Amgen alleged that the 26 examples of antibodies disclosed in the specification were structurally representative to meet the written description requirement.[131] Furthermore, the specification discloses the three-dimensional structure for two antibodies and shows where the antibodies bind to PCSK9.[132] However, instead of focusing on the written description, the court relied on a lack of enablement.[133] The court reiterated the "*Wands* factors" and emphasized the high bar for enablement requirement.[134] The court held that "enablement" meant a patent specification must enable a person skilled in the art to "reach the full scope of the claimed embodiment" without undue experimentation.[135]

Moreover, because of the large number of possible antibodies within the scope of the claims, and because the associated disclosure did not provide sufficient guidance, undue experimentation would be required to determine the possible antibodies.[136] The court further noted that it was important to consider the quantity of experimentation necessary to make and use the claimed invention, and the "functional breadth" of the claims, rather than the exact number of the embodiments.[137] In this case, the claims covered a much broader functional diversity than the disclosed examples.[138]

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125. *Amgen Inc.*, 987 F.3d at 1083.
126. *Id*. at 1086, 88.
127. *Id.* at 1080.
128. *Id*. at 1082.
129. *Amgen Inc.*, 987 F.3d at 1083.
130. *Id*.
131. *Id.* at 1080.
132. *Id*.
133. *Amgen Inc.*, 987 F.3d at 1080.
134. *Id.* at 1083.
135. *See id*.
136. *Id.* at 1086–87.
137. *Amgen Inc.*, 987 F.3d at 1080, 87.
138. *Id*. at 1087.

The court then discussed the predictability of the art.[139] The court noted that the invention was in an unpredictable industry field, and there was only evidence of a small number of antibodies that could predictably be generated.[140] Therefore, the patents did not meet the enablement requirement because undue experimentation would be required to enable the full scope of the claims.[141] Amgen petitioned for a writ of certiorari.[142] Notably, the Federal Circuit previously held that routine screening of antibodies did not amount to undue experimentation.[143] Here, however, the court held undue experimentation would be needed to screen the undisclosed species covered by the claims.[144] It seems that the Federal Circuit has created a new, more restrictive enablement test for antibody claims. Again, the court provided no guidance for determining what a representative number of species is, or what structural features would be sufficient to meet/satisfy for the disclosure requirement.

B. The More Restrictive Test: Impact on Antibody Innovations

Before *Amgen II*, when the patent claims were much broader than the associated disclosure, the court generally relied on a lack of written description to reject the claims. After *Amgen II*, it will be increasingly difficult for pharmaceutical companies to claim a broad class of antibodies to satisfy both written description and enablement requirements. Pharmaceutical companies may either narrowly claim their therapeutic antibodies or wait until they make and test a representative number of species to file the patent application.

When drafting patent claims, the general strategy is to draft claims broadly in order to get as broad protection as possible.[145] Genus claims can cover a class of antibodies based on the species' common trait (e.g., capable of binding a specific protein). However, genus claims risk a lack of disclosure. It will be easier to patent an antibody if the patentee chooses to narrowly draft the claims by only claiming the sequence of the antibody itself.[146] However, for some inventions, the specific sequence is not yet identified.

Furthermore, the patent protection is limited by only claiming a sequence of the antibody because potential antibodies with slightly different sequences

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139. *Id*.
140. *Id.* at 1087–88.
141. *Id*.
142. Amgen, Inc. v. Sanofi, Aventisub, LLC, 850 F. App'x 794, 795 (Fed. Cir. 2021).
143. *In re* Wands, 858 F.2d at 736–37.
144. *Amgen Inc.*, 987 F.3d at 1088.
145. Karshtedt et al., *supra* note 34, at 3.
146. *See* Carroll & Bijanki, *supra* note 8.

may not be covered by the claim. Competitors can easily design around and develop their antibody drugs that have slightly different structures without infringing the innovator's patent. The stricter disclosure requirement standard may cause more and more biopharmaceutical companies to develop their antibody drugs by looking at other company's antibody patents, screening from the antibody library, and finding capable antibodies with similar functions but outside the coverage of the existing patents' claims, instead of investing significant amounts of money and effort discovering novel therapeutics.

After *Amgen II*, it is very likely patent examiners will become more conservative when granting the broader antibody claims, meaning applicants would have to fight for their patent applications through appeal to the Patent Trial and Appeal Board and then the Federal Circuit.[147] As a result, companies have to spend far more time, money, and research to satisfy the new antibody patenting requirements following the *Amgen* ruling.[148] To walk around this ruling, companies may seek trade secret protection rather than patent protection and rely on the 12 years of exclusivity provided by the FDA.[149] The definition of the protectable subject matter under trade secret law is significantly broader than patent law.[150] Where patent protection is of less commercial benefit when compared to the investment, trade secret protection may be a good alternative.[151]

While relying on the 12 years of exclusivity from FDA and holding onto the invention as trade secrets may be a good option for biopharmaceutical companies, society may lose the opportunity to learn from the invention. Unlike a patent, which requires an applicant to disclose the invention in exchange for a 20-year monopoly, trade secrets require the owner to maintain the secrecy of the information. Disclosing the invention increases the opportunities for improving the invention, and the public can therefore benefit from the advance of antibody technology.

147. Kaitlyn Taylor, *The Patentability of Antibodies for Use in Medications After Amgen v. Sanofi*, 6 U. CIN. INTELL. PROP. & COMPUTER L.J. 1, 18 (2021).
148. *Id.*
149. Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021, 8:07 PM EST), https://www.law360.com/articles/1356194 [https://perma.cc/47AR-2W5M].
150. *Trade secrets / Regulatory Data Protection*, USPTO, https://www.uspto.gov/ip-policy/trade-secret-policy [https://perma.cc/784N-K2EJ].
151. *See id.*

IV. RECENT LESSONS FROM FOREIGN ANTIBODY PATENT PROTECTION

A. Japanese Treatment

Japan has a very similar disclosure requirement to the U.S. There are two requirements: enablement and support.[152] Japan's enablement requirement is equivalent to the U.S.'s enablement requirement and the support requirement is equivalent to the U.S.'s written description requirement.[153]

In *Amgen II*, Amgen's patents were held to be invalid for lack of enablement.[154] However, in the corresponding Japanese litigation of *Amgen vs. Sanofi*, the Japanese Supreme Court ruled in favor of Amgen in April 2020, upholding the Intellectual Property High Court's decision that Amgen's patents are valid and thereby disregarding Sanofi's lack of disclosure argument.[155]

The patents-in-suit were directed to PCSK9 inhibitors, which can be used to treat high cholesterol.[156] As previously mentioned, PCSK9 is a naturally occurring protein that binds to the bad cholesterol receptors that are responsible for removing bad cholesterol from our bloodstream.[157] The antibody is claimed by its function to "neutralize the binding of PCSK9 to LDLR protein and compete with a reference antibody" rather than the amino acid sequence.[158] The specification discloses the mechanism of how the antibodies can inhibit the binding of PCSK9, a method of preparing the antibody, and a method of screening other antibodies that are capable for achieving the same function.[159] With respect to the screening method, the specification describes a series of steps to obtain the claimed antibody: the production of immunized mice, the preparation of hybridomas by using immunized mice, various types of screening to identify the antibodies that can achieved the desired function, and the method for evaluating the effect of the antibodies identified through the screening.[160] The specification also

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152. JAPAN PATENT OFFICE, *supra* note 64.
153. *See id*. pt. II, ch. 1, § 2-1, ch. 2., § 2.1
154. *Amgen Inc.*, 987 F.3d at 1088.
155. Sheena Linehan, *Amgen v Sanofi: Narrowing the Scope of Protection for Antibody Inventions*, POTTER CLARKSON, https://www.potterclarkson.com/insights/amgen-v-sanofi-narrowing-the-scope-of-protection-for-antibody-inventions/ [https://perma.cc/3AH6-ZPFV].
156. Shimako Kato, *Reasonable Protection of Antibody Patents* (Apr. 26, 2019), https://fordhamipinstitute.com/wp-content/uploads/2019/04/Kato-Shimako_Reasonable-protection-of-antibody-patents-for-27th-Fordham-IP-Conferenc17042019.pdf [https://perma.cc/7FMM-55ZR].
157. *Amgen Inc*, 872 F.3d at 1371.
158. NAGOYA INTERNATIONAL, *supra* note 63.
159. *Id*.
160. *Id*.

disclosed the three-dimensional structure showing where the antibodies bind to PCSK9.[161]

The Intellectual Property High Court ruled that the patent satisfied both the support and enablement requirements.[162] To satisfy the support requirement, the patent must disclose the invention in a manner that a person skilled in the art would recognize that the problem to be solved by the invention was actually solved.[163] The patent satisfied the support requirement because it disclosed the method of preparing hybridomas that produces the claimed antibody, and the method of screening other antibodies fall within the scope of the claim.[164] The description would enable a person skilled in the art to make the claimed antibody by repeating the procedures described in the patent, and they would have recognized that the claimed antibody can reduce the risk of diseases related to high cholesterol.[165] The court also addressed the appellant's arguments that the patent failed to meet the enablement because it did not describe the amino acid sequence of the antibody. The court noted that, based on common general knowledge, a person skilled in the art can identify the amino acid sequence by obtaining the claimed antibodies.[166] Therefore, providing the amino acid sequence was not required.[167]

With respect to the enablement requirement, the court held the patent satisfied this requirement because it definitely and sufficiently described the invention in a manner that allowed a person skilled in the art to carry on the invention.[168] A person skilled in the art could prepare and use the claimed antibody based on the guidance provided in the specification of the patent.[169] The specification did not need to disclose how each and every suitable antibody may be obtained.[170] Instead, even though the person skilled in the art might need to take time and effort to obtain the antibodies within the scope of the claim, as long as the specification provided sufficient disclosure to make and use the invention, the enablement requirement was

161. *Id*.
162. NAGOYA INTERNATIONAL, *supra* note 63.
163. JAPAN PATENT OFFICE, *supra* note 64, pt. II, ch. 2, § 2.
164. NAGOYA INTERNATIONAL, *supra* note 63.
165. *Id*.
166. *Id*.
167. *Id*.
168. NAGOYA INTERNATIONAL, *supra* note 63.
169. *Id*.
170. *Id*.

met.[171] The Japanese Supreme Court later affirmed the Intellectual Property High Court's decision and rejected Sanofi's arguments for lack of disclosure.[172] Sanofi was prohibited from manufacturing, distributing, importing, or offering to distribute the infringing product (Praluent) in Japan.[173]

Overall, even though it is generally believed that JPO has strict enablement and support requirements regarding patent disclosure, it accepted genus claims defined by function without identifying the antibody structure.[174] In the U.S., however, the function defined claims in antibody patents have almost invariably been rejected by the court.[175] Based on the decision in *Amgen Inc. v. Sanofi*, the Japanese court held the disclosure requirement was fulfilled when the specification contains enough description such as the mechanism of how the claimed antibody achieved the desired results and the screening method to obtain other antibodies covered by the claim.[176] But in the U.S., if the claim is too broad or contains a large number of possible antibodies, the court may reject it due to lack of enablement and/or lack of written description, even though the specification contains detailed descriptions regarding the screening methods, and discloses many examples of the claimed antibodies.[177]

B. The European Union's Treatment

The EPO only has a "sufficiency of disclosure" requirement defined by EPC Art. 83, which is equivalent to the U.S. enablement requirement.[178] The standard is whether the patent application discloses the invention in a manner that enables a person skilled in the art to carry out the invention.[179]

According to the EPO's examination guidelines, a genus claim, even in a broad scope, may be acceptable as long as there is reasoning in the specification and the invention could extend across the entire claimed

171. *Id*.
172. Linehan, *supra* note 155.
173. Michael Sin, *Amgen: Japan Supreme Court Rejects Sanofi Appeal on PCSK9 Patent*, BLOOMBERG LAW (May 7, 2020, 9:18 PM), https://news.bloomberglaw.com/ip-law/amgen-japan-supreme-court-rejects-sanofi-appeal-on-pcsk9-patent [https://perma.cc/VMD6-4QHN].
174. *See* NAGOYA INTERNATIONAL, *supra* note 63.
175. *See* Loh, *supra* note 39.
176. *Id*.
177. *See Amgen Inc.*, 987 F.3d 1080, 1083–84 (Fed. Cir. 2021).
178. Holliday, *supra* note 79.
179. The European Patent Convention, *supra* note 78.

category.[180] The EPO has provided the level of disclosure required for antibodies based on the case law of the Boards of Appeal.[181]

In *Lay Line Genomics SpA v. Astrazeneca*, the EPO Boards of Appeal discussed the sufficiency of disclosure under EPC Art. 83.[182] The patent directed to monoclonal antibodies acting as NGF (Nerve Growth Factor)-antagonist molecules, which can be used to treat neurological pathologies.[183] The claim at issue, claim 37, was a functionally defined genus claim.[184] Claim 37 recites an antibody that can "recognize and bind the high affinity tyrosine kinase receptor of NGF," and "prevents the functional activation of TrkA by NGF."[185] The appellant argued that claim 37 failed to meet the disclosure requirement because the patent only disclosed one example (i.e., antibody MNAC13) in relation to the function indicated in claim 37.[186] Without further guidance, there would be an undue burden for a skilled person to produce other antibodies with this functional property.[187] The Board found that the disclosure of the particular monoclonal antibody, MNAC13, was sufficient.[188] The patent disclosed a detailed method for the preparation of antibody MNAC13.[189] In the Board's view, based on the disclosure of a particularly known antibody and common general knowledge, a skilled person would be able, in a possibly time-consuming but straightforward manner, to find other antibodies with the same function and properties as MNAC13.[190] The Board further noted that the sufficiency of

180. Poliana Belisário Zorza et al., *Sufficiency of Disclosure and Genus Claims for Protection of Biological Sequences: a Comparative Study Among the Patent Offices in Brazil, Europe and the United States*, 3 BIOTECH. RSCH. & INNOVATION 91, 96 (2019), https://www.sciencedirect.com/science/article/pii/S2452072118300789#bib0055 [https://perma.cc/P3HU-JP4Q].

181. *Level of Disclosure Required For Antibodies*, EUROPEAN PATENT OFFICE, https://www.epo.org/law-practice/legal-texts/html/caselaw/2019/e/clr_ii_c_7_3.html [https://perma.cc/35QU-43T2].

182. Lay Line Genomics SpA v. Astrazeneca U.K. Ltd., Decision T 0617/07 - 3.3.04, Boards of Appeal of the European Patent Office, 8 (Aug. 4, 2009), https://www.epo.org/law-practice/case-law-appeals/pdf/t070617eu1.pdf [https://perma.cc/QG7S-HXCH].

183. *Id*. at 6–7.

184. *Id.*

185. *Id*.

186. *Lay Line Genomics SpA*, *supra* note 182, at 9–10.

187. *Id*.

188. *Id.* at 28.

189. *Id.* at 25.

190. *Id.* at 25–29.

the disclosure would not always to be denied if there was only one example of carrying out an invention.[191]

In *Washington University St. Louis v. Neuralab Ltd.*, the EPO Boards of Appeal addressed the concept of the sufficiency of disclosure over the whole scope of the claim.[192] Washington University St. Louis owned a patent directed to humanized antibodies that have framework sequences.[193] The patent disclosed a specific humanized version of the antibody — Hu266, and many alternatives.[194] Therefore, the opponent had the burden to prove the invention could not be carried out.[195] The opponent argued that a skilled person could not make additional humanized antibodies that were different from the disclosed example—Hu266.[196] However, the Board noted that, based on the results of the experiment disclosed in the patent, the specific example—humanized antibody Hu266—had good binding properties.[197] Therefore, it could be used as a guide to find and make other functional humanized antibodies fall within the scope of the claim.[198]

According to EPO case law, a patent disclosure is only considered sufficient under EPC Art. 83 if a skilled person can obtain substantially all embodiments falling within the whole scope of the claim.[199] However, the Board pointed out that "sufficiency of disclosure over the whole scope of the claim" did not mean that a disclosure must demonstrate each and every conceivable embodiment of a claim could be obtained.[200] The skilled person could use his or her common general knowledge to carry out the invention.[201] The Board further noted that the disclosure would fail only if there was no single method to obtain the variants at issue.[202] Considering the number of examples disclosed by the patent, the Board concluded that the EPC Art. 83 requirement was fulfilled.[203]

In a 2021 case, the EPO Boards of Appeal allowed an antibody claim based solely on functional definitions.[204] The patent at issue directed to

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191. *Id.* at 29.
192. *See* Wash. Univ. St. Louis et al. v. Neuralab Ltd., Decision T 0386/08 - 3.3.04, Boards of Appeal of the European Patent Office, Decision 19 (Nov. 4, 2010), https://www.epo.org/law-practice/case-law-appeals/pdf/t080386eu1.pdf [https://perma.cc/Y36J-QGQ6].
193. *Id.* at 2.
194. *Id.* at 10.
195. *Id*.
196. *Wash. Univ. St. Louis et al*., *supra* note 192, at 10.
197. *Id.* at 11.
198. *Id.*
199. *Id.* at 41.
200. *Wash. Univ. St. Louis et al.*, *supra* note 192, at 41.
201. *Id.* at 43.
202. *Id*.
203. *Id.* at 42.
204. *See Lay Line Genomics SpA*, *supra* note 182, at 3.

monoclonal antibodies against NKG2A, a receptor for natural killer cells.[205] The genus claim recites a monoclonal antibody or fragment that (a) specifically binds to NKG2A but not the related receptors NKG2C and NKG2CE and (b) binds the same epitope on NKG2A as a deposited antibody.[206] While the sufficiency of disclosure was not addressed in this case, it is notable that the EPO Boards of Appeal accepted this format of genus claims.[207] However, in the equivalent U.S. case, following *Amgen Inc. v. Sanofi* (2021), the examiner rejected such claims for lack of written description to demonstrate that the applicant was in possession of the claimed genus of monoclonal antibodies.[208] The EPO Boards of Appeal held that functionally defined claims have generally been accepted in Europe, such as claims to "an antibody that binds a specific epitope on the antigen CD47, and thereby inhibits the function of CD47,"[209] and claims to an antibody that can "recognize and bind the high affinity tyrosine kinase receptor of NGF," and "prevents the functional activation of TrkA by NGF."[210]

In summary, the European patent system accepts functionally defined claims, while the USPTO tends to reject them for lack of written description.[211] The EPO generally requires fewer examples to be disclosed to enable the full scope of the claims.[212] The European treatment provides a balance between not removing the information from the public domain and not depriving the patentee of a fair monopoly by disclosing the invention. On the other hand, examiners in Europe are strict with the level of data required to demonstrate the claimed antibodies indeed obtain a novel therapeutic effect.[213] Therefore, it is important to disclose representative data in U.S. and European patent applications.

Notably, there is a trend that antibody drug inventions with no sequence limitations are registered more in Europe and Japan, rather than in the U.S.[214]

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205. *Id*.
206. *Id*.
207. *Patenting Antibodies in the US and Europe*, HGF (May 2022), https://www.hgf.com/healthcare-scanner/patenting-antibodies-in-the-us/ [https://perma.cc/NZA3-NT5P].
208. *Id*.
209. *Id*.
210. *See Lay Line Genomics SpA*, *supra* note 182, at 6.
211. *See Patenting antibodies in the US and Europe*, *supra* note 207.
212. *See Belisário Zorza et al*., *supra* note 180, at 96.
213. *See Patenting antibodies in the US and Europe*, *supra* note 207.
214. *See* NAGOYA INTERNATIONAL, *supra* note 63.

C. Canadian Treatment

As noted earlier, according to the Canadian Patent Act, the disclosure requirement has two elements: enablement and written description.[215] Canada has a less strict disclosure requirement in view of the amended Canadian Intellectual Property Office (CIPO)'s Manual of Patent Office Practice in 2009.[216] Based on the amendment, Canada allows claims directed to monoclonal antibodies in the absence of working samples if the process of making such antibodies is known in the art.[217]

Re Immunex Corporation Patent Application No. 583,988 is the first time that the Commissioner of Patents granted antibody claims without a working sample in the patent specification.[218] The subject matter of the application related to cytokine receptors (i.e., IL-1R polypeptides).[219] The claims at issue directed to monoclonal antibodies immunoreactive with IL-1R polypeptides.[220] The commissioner addressed whether the antibodies met the enablement requirement and the written description requirement.[221] The monoclonal antibody claims would be considered as enabled if they disclosed the specific antigen (i.e., Type I IL-1R polypeptides) it binds to.[222] The Commissioner noted that the specification disclosed the actual construction, expression and purification of Type I IL-1R polypeptides, and that a skilled person would have been able to make the monoclonal antibodies based solely on the specification.[223] Therefore, the claims would meet the enablement requirement if they were limited by reference to Type I IL-1R polypeptides.[224]

The Commissioner then discussed the written description requirement.[225] The Commissioner acknowledged that in foreign jurisdictions, claiming an antibody by describing the novel antigen to which it binds is allowed even if the specification provides no working example of the production

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215. Patent Act, R.S.C. 1985, c P-4, § 27(3) (Can.).
216. Luca & Trifonova, *supra* note 96, at 868.
217. *Id*.
218. Sally A. Hemming, *Canadian Patent Office Grants Claims to Monoclonal Antibodies Without a Working Example*, SMART & BIGGAR (June 22, 2011), https://www.smartbiggar.ca/insights/publication/canadian-patent-office-grants-claims-to-monoclonal-antibodies-without-a-working-example [https://perma.cc/38WR-YT6G].
219. *In re Immunex Corporation* No. 583,988, Dec. Comm'r Pat. (2010) at ¶ 3, https://www.smartbiggar.ca/_Archives/files/Patent%20No.%20583,988.pdf [https://perma.cc/9XKF-THSF].
220. *Id.* ¶ 5.
221. *Id.* ¶ 54–70.
222. *Id*. ¶ 54.
223. *In re Immunex*, *supra* note 219, ¶ 58.
224. *Id.* ¶¶ 54, 59.
225. *Id.* ¶ 60.

of the antibody itself.[226] Therefore, the applicant can claim monoclonal antibodies that are immunoreactive with the polypeptide without disclosing a specific example, as with the described novel Type I IL-1R polypeptides.[227] Such claims would not necessarily need to be restricted to one species of monoclonal antibody and the broad claims were acceptable.[228] The specification provided sufficient description of the Type I IL-1R polypeptides by disclosing two examples with the complete amino acid sequence, maturation sites, molecular weight, and DNA sequences.[229] However, the Commissioner noted that in cases where the antigen is complex, the antigen has substructures or epitopes common to a known antigen, or the claimed antibodies are therapeutic or diagnostic antibodies, more detailed information for preparation and characterization may be required.[230]

It is noteworthy that the Canadian court endorsed consistency with other common-law jurisdictions and allowed claiming an antibody specific for a novel antigen without providing a working example of the antibody itself.[231] In contrast, the U.S. Federal Circuit rejected the so-called "newly characterized antigen test" in 2017 and required patentees to disclose sufficient information about the claimed antibody itself.[232]

The Canadian Federal Court addressed the disclosure requirement for antibody patents in *AbbVie v. Janssen* in 2014.[233] This case is the first time the Canadian Federal Court provided guidance on validity and infringement issues of therapeutic antibodies.[234] The patent-in-suit directed to human antibodies that bind IL-12, a cytokine that regulates immune reactions in the body.[235] The antibodies can be used to treat acute and chronic diseases.[236] The claims at issue recite "the use of a neutralizing isolated human antibody . . . that binds to human 1L-12 and dissociates from human IL-12…."[237] The specification disclosed one type of structurally similar

226. *Id.* ¶ 64.
227. *In re Immunex*, *supra* note 219, ¶ 68.
228. *Id*.
229. *Id.* ¶ 70.
230. *Id.* ¶ 69.
231. *Id.* ¶ 68.
232. *See Amgen Inc.*, 872 F.3d at 1376–78.
233. AbbVie Corp. et. al. v. Janssen Inc., [2014] 1 F.C. 55, ¶ 166 (Can. F.C.).
234. Luca & Trifonova, *supra* note 96, at 869.
235. *AbbVie Corp*. et. al., *supra* note 233, ¶ 1.
236. *Id.* ¶ 124.
237. *Id.* ¶¶ 46–47.

antibodies that bound IL-12.[238] The court discussed whether the claims met the disclosure requirement when only one type within the genus was disclosed.[239] The court noted a single type of antibody could, in some cases, satisfy the disclosure requirement.[240] The court further found the functionally defined genus claims were valid.[241]

However, in the similar U.S. litigation of *AbbVie v. Janssen*, the Federal Circuit affirmed the district court's decision and held the functionally defined antibody claims were invalid for failure to meet the written description requirement under 35 U.S.C.S. § 112.[242] The court held that even though AbbVie disclosed a high quantity of species having 1L-12 binding affinities, the described species were all similar in structure and did not support the whole genus.[243] In technology industries that are highly unpredictable, functionally defined genus claims can be inherently vulnerable to inadequate written description challenges because it would be difficult to demonstrate the correlation between structure and function for the whole genus.[244]

V. SUGGESTIONS FOR MOVING FORWARD

Previously, the United States incentivized investment in the biopharmaceutical industry by providing broad patent protections to inventions related to therapeutic antibodies.[245] However, recent U.S. case law has tightened the disclosure requirement for antibody patents and slighted the ability to obtain broad protection of therapeutic antibodies.[246] A patent claim can be rejected for lack of written description and/or enablement even if the patent specification explicitly discloses the three-dimensional structure of the claimed antibody and a variety of working samples.[247] Unless courts or Congress reverse this trend and adopt a less restrictive disclosure requirement for antibody patents, biopharmaceutical companies may be discouraged from investing in antibody technology where the patent protection is of limited commercial benefit.[248]

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238. *Id.* ¶¶ 166–67.
239. *AbbVie Corp*. et. al., *supra* note 233, ¶ 166.
240. *Id.* ¶¶ 166–67.
241. *Id.* ¶ *2.*
242. Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1304–05 (Fed. Cir. 2014).
243. *Id*. at 1298–99.
244. *Id.* at 1301.
245. *See* James F. Haley, Jr., Karen Mangasarian & Brian M. Gummow, *Written description: a Death Knell to Genus Claims in Biotechnology* (Aug. 25, 2022), [https://perma.cc/34JV-J4WW].
246. *See id.*
247. *See Abbvie Deutschland*, 759 F.3d at 1304–05.
248. Haley, *supra* note 245.

A. Solutions for Patentees

As discussed above, broad antibody genus claims risk lack of disclosure. The rejection of the newly characterized antigen test means that when the antibodies themselves are not adequately disclosed in the patent specification, patentees are no longer able to get broad claims to a genus of antibodies capable of binding a target antigen.[249] In view of the risks, antibody patentees should provide as much detail of structure features and properties as possible in the patent specifications.[250] If patentees decide to claim antibodies by function alone, it is necessary to disclose a representative number of working examples that can support the breadth of the claims. However, what counts as a representative number of examples is still an open question. Therefore, biopharmaceutical companies likely need far more research and data to support the broad claims.

Another option is to claim the amino acid sequences for a sequenced antibody. It will be easier to meet the disclosure requirement and get a patent. However, patentees can only obtain narrow patent protections because antibodies with slightly different amino acid sequences may not be covered by the claim. It will be important for biopharmaceutical companies to implement strategies to balance the amount of experimentation and investment needed and to decide whether to proceed with broad claims or narrow claims.

B. The U.S. Supreme Court Should Strike Down the Federal Circuit's Stricter Disclosure Requirements for Antibody Patents

Based on the recent ruling on antibody genus claims, I argue the Federal Circuit has significantly altered the meaning of enablement under 35 U.S.C. §112(a) to restrict the scope of genus claims. The move to invalidate issued antibody patents will greatly dissuade antibody inventions and endanger the patent protection of current patented medications. The Supreme Court should overturn the Federal Circuit's decision in *Amgen Inc. v. Sanofi* and reject the over-restrictive disclosure requirement for antibody genus claims.

The goal of the enablement requirement is to allow a person with ordinary skills in the art to make and use the invention without undue

249. *See* Loh, *supra* note 39.
250. *Id.*

experimentation.[251] However, the Federal Circuit has changed this requirement into allowing a person with ordinary skills in the art to discover and make every antibody within the scope of the claims.[252] The court has traditionally allowed claims requiring some experimentation, so long as the experimentation is not unduly extensive.[253]

However, in *Amgen II*, the Federal Circuit held undue experimentation would be needed to screen the undisclosed species covered by the claims, even though the patent specification had described detailed steps of screening other antibodies that are capable of achieving the function.[254] Based on the disclosure of specific working examples, the method to prepare the antibody, and the screening method to find other capable antibodies, a skilled person would be able to make and use the invention without undue burden. Therefore, the Federal Circuit has created a new goal and higher bar for the enablement requirement, which is inconsistent with the court's previous rulings and the statutory language of §112(a). Additionally, the standard for written description was also increased based on the ruling of *Amgen*, where the court found 26 examples of antibodies to be insufficient to be considered "a representative number of species."[255]

In the last thirty years, the Federal Circuit has regularly reversed district courts' rulings that have found sufficient support for antibody genus claims.[256] The Federal Circuit has thrown out billion-dollar jury verdicts due to a lack of disclosure on three occasions.[257] This trend may greatly threaten antibody innovation when increasingly more antibody genus claims are declared invalid in court. The stricter standard for both the enablement and written description requirements creates great challenges in regard to the innovation and patentability of therapeutics antibodies.[258] Companies have to invest more time, money, and research to satisfy the new antibody patenting requirements following the *Amgen* ruling.[259]

The difficulty of obtaining and enforcing antibody patents will move companies toward seeking trade secret protection.[260] The FDA provides a

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251. *See In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987).

252. *See Amgen Inc.* at 1087–88.

253. *See* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984).

254. *See Amgen Inc.*, 987 F.3d 1080 at 1082, 1088.

255. *Id.* at 1083.

256. Karshtedt et al., *supra* note 34, at 4.

257. *Id.*

258. Kass, *supra* note 149.

259. *See* Taylor, *supra* note 147, at 18.

260. Dustin Weeks et al., *How the Supreme Court's Clarification of Enablement in Amgen May Affect the Future of Patent Law*, TROUTMAN (Nov. 29, 2022), https://www.

twelve-year exclusivity period for biologics, and companies may skip the patents and hold onto their inventions as trade secrets.[261] While this may be a good option for companies, the public may lose the opportunity to learn from the new technological advances. Patenting therapeutic antibodies must be encouraged so the public can benefit from the knowledge dissemination. But for patients, there could be some benefits to the higher bar of the disclosure requirement.[262] The decision might promote competition, and therefore lower drug prices.[263]

Nevertheless, the Federal Circuit's overly restrictive standard created by the Federal Circuit would inspire imitators to use it as a defense against patent holders enforcing their patents and could lead them to lose their core patents. This would be inconsistent with the goal of patent law to promote the progress of science and useful arts, and it would endanger the protection of current patented antibody drugs. Furthermore, the financial cost of the overly restrictive standard will cause delayed innovation in antibody technology, including delays in research and development of life-saving cancer therapies.[264]

The U.S. previously incentivized investment and innovation by providing broad patent protections to inventors.[265] However, the decision in *Amgen II* suggests that the U.S. has adopted a more restrictive standard than other major jurisdictions. Japan has two requirements for adequate disclosure, which is essentially similar to the enablement and written description requirement in the U.S..[266] While Japan accepts function-defined claims without identifying the antibody structure,[267] functional claiming for antibodies without disclosure of the structure have almost invariably been rejected in the U.S..[268] The European Union only has one disclosure requirement—enablement, and it accepts functional claims.[269] Canada also

troutman.com/insights/how-the-supreme-courts-clarification-of-enablement-in-amgen-may-affect-the-future-of-patent-law.html [https://perma.cc/LG9H-JRLZ].

261. Kass, *supra* note 149.
262. *Id.*
263. *Id.*
264. Krisha Yadav-Rajan, *Patenting Antibodies: A Complication in Written Description Jurisprudence*, 21 DEPAUL J. HEALTH CARE L. 1, 23, 24 (2020).
265. *See* Haley, *supra* note 245.
266. *See* YANAGIDA & ASSOCS., *supra* note 69.
267. *Id*.
268. Karshtedt et al., *supra* note 34, at 23.
269. *See* Holliday, *supra* note 79.

has enablement and written description requirements for antibody patents,[270] however, case law shows that Canada has a less restrictive standard than the U.S. because Canada allows antibody claims without a working sample if the process of making such antibodies is known in the art.[271]

While the U.S. Federal Circuit rejected the "newly characterized antigen test" in 2017,[272] Europe and Canada still allow claiming an antibody specific for a novel antigen without providing a working example of the antibody itself.[273] Recent trends show that antibody drug inventions without defining the amino acid sequence are registered more in Europe and Japan, rather than in the U.S.[274] To keep the U.S. at the forefront of therapeutic antibodies, the court must shift to adopt some of the treatment demonstrated in the countries outlined here to promote the continued innovation in the field of antibody drugs.

The U.S. Supreme Court should strike down the overly restrictive standard for disclosure regarding antibody patents. Specifically, the Supreme Court should reject the new enablement test created by the Federal Circuit in *Amgen II*. With respect to the written description requirement, the Supreme Court should deal with the threshold question of the "representative number of species." Over the years, the Federal Circuit has failed to provide instruction about what number or type of species satisfies the "representation" of the entire genus. The Supreme Court should address this open question and provide enough guidance to support the development of innovative therapeutics.

C. New Provision to 35 U.S.C.

If the Supreme Court upholds the Federal Circuit's decision in *Amgen II*, Congress should address the issue by introducing a new provision to 35 U.S.C. to carve out an exception for disclosure requirement of antibody patents.[275] The new provision should define "undue experimentation" for the enablement requirement. Congress should recognize that enablement is met if the patent specification has provided adequate guidance for how to prepare and use the claimed antibody and the steps to screen other capable antibodies, even though the person skilled in the art may need to take some time and effort to carry out the claimed antibody. Additionally, the new provision should provide instruction as to how many or what types of disclosed species are sufficiently representative.

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270. Patent Act, R.S.C. 1985, c. P-4, § 27(3) (Can.).
271. *See* Luca & Trifonova, *supra* note 96, at 868.
272. *See Amgen Inc.*, 872 F.3d at 1376–78.
273. *See* Luca & Trifonova, *supra* note 96, at 868.
274. NAGOYA INTERNATIONAL, *supra* note 63.
275. Yadav-Rajan, *supra* note 264, at 22.

VI. CONCLUSION

A recent line of case law in the U.S. has rendered the enablement and written description requirements for antibody patents to be more stringent than in other major jurisdictions, including the European Union, Japan, and Canada. Noteworthy, the Federal Circuit's decision in *Amgen v. Sanofi* (2021) created an overly restrictive disclosure requirement for antibody genus claims and significantly changed the U.S. patent system regarding the patentability of antibodies.[276] The *Amgen* decision has therefore slighted the ability to obtain broad protection of therapeutic antibodies. In contrast, the capability is more permissive in European Union, Japan, and Canada.

Overall, newly introduced antibody drugs have achieved massive success in treating different diseases. Patent protection is essential for the entire biotechnology industry. The *Amgen* decision has and will significantly impact the patentability of antibodies and make obtaining and enforcing antibody patents increasingly difficult. More companies will instead seek trade secret protection to avoid this hurdle, which will remove a potentially large segment of further innovation from the public. Unless the Supreme Court or Congress reverses this trend and adopts a less restrictive disclosure requirement for antibody patents, biopharmaceutical companies may be discouraged from investing in antibody technology. Therefore, the Supreme Court should reverse the Federal Circuit's decision in *Amgen II* and provide instructions on the number or type of species that satisfies the "representation" of the entire genus. Alternatively, Congress should enact a new section to the Patent Act to establish a less restrictive disclosure requirement for antibody patents.

276. Taylor, *supra* note 147, at 28.